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09/995,246	11/26/2001	Kenji Yamazaki	83378.0001	1370
26021	7590	10/04/2004	EXAMINER	
HOGAN & HARTSON L.L.P.			KUMAR, ARADHANA	
500 S. GRAND AVENUE			ART UNIT	PAPER NUMBER
SUITE 1900			3762	
LOS ANGELES, CA 90071-2611				

DATE MAILED: 10/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/995,246

Applicant(s)

YAMAZAKI ET AL.

Examiner

Aradhana Kumar

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 April 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 4/5/04 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 10/20/2003.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Drawings***

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 144, 146, 168, 172. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

In addition to Replacement Sheets containing the corrected drawing figure(s), applicant is required to submit a marked-up copy of each Replacement Sheet including annotations indicating the changes made to the previous version. The marked-up copy must be clearly labeled as "Annotated Marked-up Drawings" and must be presented in the amendment or remarks section that explains the change(s) to the drawings. See 37 CFR 1.121(d). Failure to timely submit the proposed drawing and marked-up copy will result in the abandonment of the application.

### ***Specification***

2. The abstract of the disclosure is objected to because:

- a. It is over 150 words in length.
- b. Page 25, line 26: it is suggested that “outer tube” be changed to “a cable including an electric wire.”

Correction is required. See MPEP § 608.01(b).

3. The disclosure is objected to because of the following informalities:

- a. Page 17, line 23: the reference numbers 126 and 128 are not shown in the drawings.

Appropriate correction is required.

***Claim Objections***

4. Claim 9 is objected to because of the following informalities: on line 3 it is unclear whether “...formed of an elastic material...” refers to the tubes or to the caps. It is suggested to use something similar to “...protective tubes which are formed of an elastic material, engage the caps, and are attached to an outside of the outer tube.”

Claim 16 is objected to because of the following informalities: on lines 4-5, it is unclear what is meant by “...a signal detected at a position of the blood pump.” It is suggested to use something similar to “...a signal detected at a location within the blood pump.”

Claim 20 is objected to because of the following informalities: on lines 4-5, it is unclear what is meant by “...for connecting a blood pump and a controller the blood pump...” It is suggested to use something similar to “...for connecting a blood pump and a controller...”

Appropriate correction is required.

5. The claims are generally narrative and indefinite. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

Regarding claim 3, the recitation "...wherein the external equipment is equipment, out of equipment that is used as one of artificial internal organs..." is awkward.

As to claim 8, the recitation "...attached to an outside of an engaging part where one end of the outer tube engages a socket for the internal equipment and to an outside of an engaging part where another end of the outer tube engages a socket for the external equipment" is awkward.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1, 8 and 10-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The preambles to claims 1 and 10 infer that a tube unit alone is to be set forth, yet the recitation "...a cable including an electric wire connected to the internal equipment..." (on lines 5 and 6 of claim 1, and on line 6 of claim 10) implies that the combination of the tube unit and the internal equipment is being claimed, making the scope of the claims unclear. The examiner will assume that the claims are directed to just the tube unit when considering the claims on the merits. If the subcombination of the tube unit is to be set forth, the examiner suggests correcting this error by referring to the connection in a functional sense such as "...an electric wire for connecting to the internal equipment..." or "...an electric wire adapted to be connected to the internal equipment..." If it was the applicants' intent to recite the combination, then the

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preambles should be amended to refer to a system, and the bodies of the claims should be amended to include a positive recitation of the internal equipment.

Regarding claim 8:

a. The preamble infers that a tube unit alone is to be set forth, yet the recitation "...engaging part..." on lines 3-5 of the claim implies that the combination of the tube and the engaging part is being claimed, making the scope of the claim unclear. The examiner will assume that the claim is directed to just the tube unit when considering the claim on the merits. If the subcombination of the tube unit is to be set forth, then the "engaging part" must be positively recited.

b. It is unclear whether the claim refers to one or two engaging parts.

c. The claim recites "engaging a socket for the internal/external equipment," and it is unclear whether this implies that the internal/external equipment has a socket. If the internal/external equipment has a socket, then it should be recited in the claim.

Claim 11 is objected to because of the following informalities: on line 5, "connected to the blood pump" implies that the combination of the tube unit and the blood pump is being claimed, making the scope of the claim unclear. The examiner will assume that the claims is directed to just the tube unit when considering the claim on the merits. If the subcombination of the tube unit is to be set forth, the examiner suggests correcting this error by referring to the connection in a functional sense such as "...for connecting to the blood pump..." If it was the applicants' intent to recite the combination, then the preamble should be amended to refer to a system, and the body of the claim should be amended to include a positive recitation of the blood pump.

7. Claim 9 recites the limitation "the caps" in line 2. There is insufficient antecedent basis for this limitation in the claim. The examiner will assume that the claim is dependent upon claim 8 when considering the claim on the merits.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-6, 8-13, 16-17, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Mori et al. (Pat. No. 6,123,726).

Regarding claim 1, Mori et al. disclose the tube unit having inner tubes (elements 24 and 25) connected between internal equipment (element 1) and external equipment (element 45), a cable (element 71) connected to element 1, and an outer tube (element 72) which accommodates the inner tubes and the cable (see Figure 11 and the associated text in column 13).

As to claims 2 and 3, Mori et al. recite a ventricular assist device (element 1) and external equipment (element 45), respectively.

Regarding claim 4, Mori et al. disclose a cable (element 71) which drives the internal equipment (element 1).

As to claims 5 and 6 and Mori et al. disclose inner tubes (elements 24 and 25). In claim 5, the applicant is not claiming the material that travels in the tube, but is simply claiming a tube capable of supplying medication, lubricant, and/or coolant. Broadly interpreted, any tube would be capable of supplying these materials. Similarly in claim 6, the applicant is not claiming the

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channel through which liquid can flow, but is simply claiming a tube which allows a liquid to flow through the channel in the tube. Broadly interpreted, any tube would include a channel through which liquid could flow.

With respect to claim 8, Mori et al. recite caps (element 80; line 45 column 6).

Regarding claim 9, Mori et al. disclose the expandable protective tube (element 72; line 50, column 3).

Concerning claims 10 and 11, Mori et al. recite inner tubes (elements 24 and 25), a cable (element 71), and an outer tube (element 72).

With regard to claim 12, Mori et al. disclose the tube unit (element 72) comprising two inner tubes (elements 24 and 25).

As to claim 13, on line 50 of column 15, Mori et al. disclose the purge solution as water, physiological saline, and a disinfectant.

Regarding claim 16, Mori et al. disclose the cable (element 71) to electrically control the drive of the blood pump (element 1).

As to claim 17, Mori et al. disclose the outer tube (element 72). It is essential that the outer tube be constructed from a biocompatible material because the tube is placed inside the living body.

Regarding claim 20, Mori et al. disclose a blood pump (element 1), a controller (element 30) to control the blood pump, and a tube unit according to claim 11.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:



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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mori et al. in view of Farley et al. (Pat. No. 6,152,899). Regarding claim 7, Mori et al. disclose the claimed invention except for a wire. Farley et al. teach that it is known to insert a wire into a tube to prevent elongation of the tube (line 15, column 10). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the tube as taught by Mori et al. with the wire as taught by Farley et al. since such a modification would prevent elongation of the tube.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mori et al. in view of Gealow (Pat. No. 5,222,980). Mori et al. disclose the claimed invention except for a tube of polycarbonate urethane, silicone, or polytetrafluoroethylene. Gealow teaches that it is known to use silicone tubes (line 36, column 7). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the tubes as taught by Mori

et al. with silicone tubes as taught by Gealow since it was known in the art that silicone could be used to manufacture flexible, biocompatible tubes.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mori et al. in view of Feingold (Pat. No. 4,784,646) and further in view of Hollingshead (Pat. No. 5,698,413). Mori et al. disclose the claimed invention except for a double-layer tube having polyvinylidene fluoride on an inside and thermoplastic polyurethane on an outside and a double-layer tube having polyvinylidene fluoride on an inside and polycarbonate urethane on an outside. Feingold teaches that it is known to use double-layer tubes (line 27, column 3) where the outer tubing is made from an elastomer such as polyurethane (line 23, column 2). Hollingshead teaches that it is known to use tubes made from polyvinylidene fluoride (line 47, column 14). At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use polyvinylidene fluoride on an inside and thermoplastic polyurethane on an outside and to use polyvinylidene fluoride on an inside and polycarbonate urethane on an outside because the applicants have not expressed criticality to the use of the recited arrangement. One of ordinary skill in the art, furthermore, would have expected the applicants' invention to perform equally well with any two biocompatible materials used for the double-layer tubes because any two biocompatible materials used for the tubes would prevent thrombus or coagulation formation. Therefore, it would have been an obvious matter of design choice to modify Mori, Feingold, and Hollingshead to obtain the invention as specified in claim 15.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mori et al. in view of Porier et al. (Pat. No. 4,118,806). Mori et al. disclose the claimed invention except for a

tube subjected to a flocking process. Porier et al. teach that it is known to use flocked tubes to promote the development of a biological interface (line 44, column 1). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the tubes as taught by Mori et al. with the flocked tube as taught by Porier et al. since such a modification would prevent infection.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mori et al. in view of Zytkevich et al. (Pat. No. 5,056,528). Mori et al. disclose the claimed invention except for a tube filled with silicone gel. Zytkevich et al. teach that it is known to fill tubes with silicone gel (line 13, column 2). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the tubes as taught by Mori et al. with the gel-filled tubes as taught by Zytkevich et al. since such a modification would eliminate the need to purge the tubes (line 23, column 1).

### ***Conclusion***

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Hoffmann et al. Pat. No. 5,902,329

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Kumar whose telephone number is 703-305-0494. The examiner can normally be reached on 7:30am - 5pm Monday - Friday.

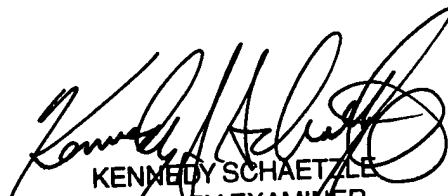
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703-305-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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KENNEDY SCHAEETZLE  
PRIMARY EXAMINER  
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